

September 22, 2008

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Japan

ECI has Succeeded in Production of Cancer Drug for Clinical Trial (ECI301)

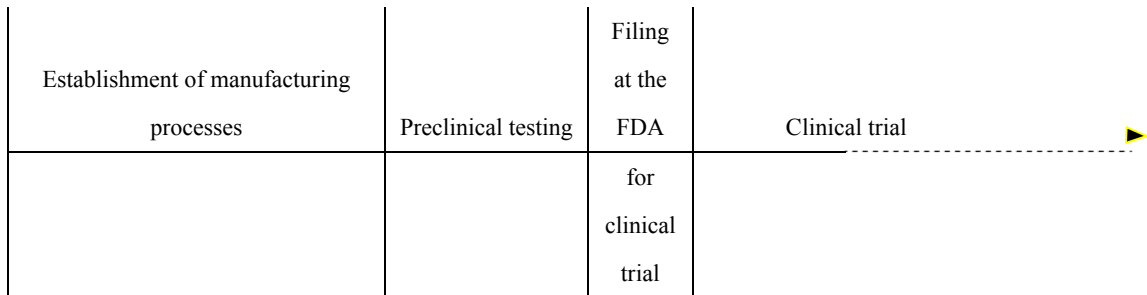
ECI, Inc is pleased to announce that it has successfully achieved mass production of the active pharmaceutical ingredient (API) for clinical trial of ECI301, a cancer drug under development, in compliance with GMP^{*1} requirements.

AGC^{*2} (Asahi Glass Co., Ltd.), to whom we entrusted the production of the API for clinical trial of ECI301, a protein drug^{*3}, has finally succeeded in producing the API in a sufficient supply volume for clinical trial, using its proprietary protein production system called ASPEX^{*4} using a yeast host.

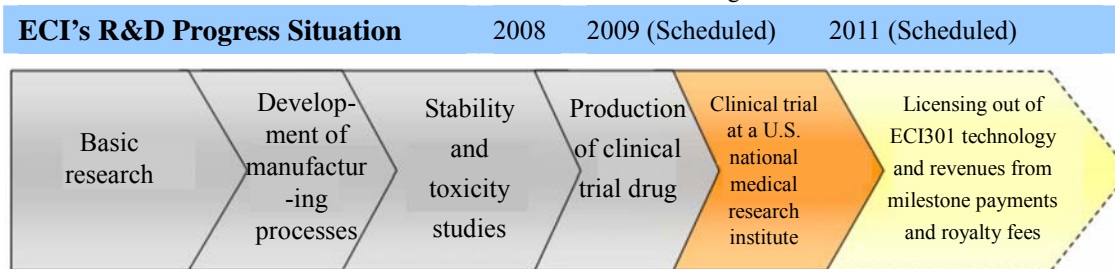
We have been concentrating our energies upon development of the cancer drug ECI301. Now it receives high expectation because of its remarkable, unique therapeutic effects^{*5}, such as drastic reduction or even perfect remission of tumor and life-prolonging effect when combined with radiotherapy, and prevention of tumor growth at non-irradiated sites (abscopal effect^{*6}), an effect not recognized in any other existing anticancer drugs. In addition, chemotherapeutics which are the principal therapy for cancers at present involves serious side effects (immunosuppressive effects, hair loss or body weight loss). Unlike existing chemotherapeutic drugs (anticancer drugs), ECI301 is a biological drug manufactured from human macrophage inflammatory protein 1 α (MIP-1 α), which is a variant chemotactic cytokines (chemokine) that are present in human body and produce immunoactivation. The various toxicity studies conducted according to GLP^{*7} have demonstrated that ECI301 does not produce harmful side effects as caused by existing anticancer drugs.

With the successful mass production achieved this time, we will file for Investigational New Drug (IND) at the FDA (U.S. Food and Drug Administration) before the end of January 2009. We are going ahead to the next stage of development toward the clinical trial (Phase I trial) of ECI301 for various kinds of tumors currently treated by radiotherapy (lung cancer, mammary cancer, prostatic cancer, uterus cancer, head and neck cancers, etc.) to be carried out at one of U.S. national medical research institutes, which is expected to start in the coming spring.

ECI301 Drug Discovery/Development Phases



We are at this stage



Expected Effects on Business Performance

We expect sales of around 500 million yen from the ECI301 project for FY2008 (ending May 31, 2009), which figure on lump-sum, up-front contract money that we will receive upon entering into license agreements for ECI301 with global pharmaceutical companies with whom we are under negotiation. This sales estimate has already been included in the projected business performance disclosed on July 15 this year.

Actual effects of the ECI301 project upon the company's business performance will be announced as soon as they become evident.

Glossary

*1: GMP

GMP stands for Good Manufacturing Practice and is a standard recognized worldwide for the control and management of manufacturing and quality control of pharmaceutical and quasi pharmaceutical products, established and enforced to ensure quality of these products in accordance with the Drugs, Cosmetics and Medical Instruments Act and other applicable laws (in case of Japan).

*2: AGC (Asahi Glass Co., Ltd.)

Given below is a brief corporate profile of AGC:
 Head Office: 1-12-1, Yurakucho, Chiyoda-ku, Tokyo, Japan
 President & COO: Kazuhiko Ishimura

Founded: September 8, 1907

Major Business Areas: Manufacturing of glasses and displays, chemicals, electronics and energy related products

Capital: 90,859 million yen (as of December 31, 2007)

Sales: Non-consolidated: 634.8 billion yen; Consolidated: 1,681.2 billion yen (FY ending December 31, 2007)

Employees: Non-consolidated: 5,840; Consolidated: 49,710 (as of December 31, 2007)

*3: Protein drug (Biological or biotherapeutic drug)

Unlike existing chemotherapeutic drugs, a protein drug is designed by the latest biotechnology using biological ingredients. To date several protein drugs have been launched on the market, all of which have been recognized as being very effective.

*4: ASPEX

ASPEX stands for Asahi Glass *Schizosaccharomyces pombe* Expression System.

*5: About the remarkable, unique therapeutic effects of ECI301, please read the monograph appearing in *Clinical Cancer Research*, a leading journal on cancer research studies in the United States, the February 2008 Issue, Vol. 14, Num. 4, pp. 1159-1166. (Collaborative research between the Graduate School of Medicine, the University of Tokyo and Department of Radiology, the University of Tokyo Hospital.)

*6: Abscopal effect

The abscopal effect refers to a reaction (reduction or eradication of tumor) produced following irradiation in the cancer radiotherapy but occurring outside the zone of actual radiation absorption, and is a rarely recognized clinical event.

It has already been demonstrated that ECI301 consistently induces the abscopal effect of radiation and that multiple immunocompetent cells are involved in the effect. The abscopal effect is expected to be effective also for distant metastatic cancers.

*7: GLP stands for Good Laboratory Practice and covers the code of practice for laboratories conducting non-clinical studies for assessment of the safety of pharmaceutical products in accordance with the Drugs, Cosmetics and Medical Instruments Act and other applicable laws (in case of Japan).

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